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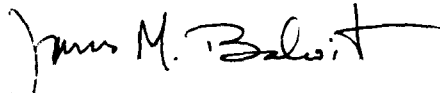
October 30, 2002

Dear Madam, dear Sir:

Enclosed please find one copy of the final printed version of our white paper, *Evaluation Criteria for Guarded Fistula Needles for Hemodialysis*, which we submitted September 16, 2002 in response to the November 2000 petition to the FDA by the Public Citizen's Health Research Group and the Service Employees International Union to ban certain sharps devices. We have made several minor revisions to this final document.

To simplify your posting of our white paper in your dockets, feel free to download the file from <http://www.ahrensbalwit.com>.

Sincerely,



James M. Balwit  
President

OIP-0120

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# Evaluation Criteria for Guarded Fistula Needles for Hemodialysis

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# Evaluation Criteria for Guarded Fistula Needles for Hemodialysis

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The federal Needlestick Safety and Prevention Act (NSPA) of 2000 was designed to protect healthcare workers (HCWs) from occupational exposure to needlestick injuries (NSI) and exposure to infectious materials by mandating Occupational Safety and Health Administration (OSHA) regulations on the use of safety engineered sharps devices. Recently, public interest groups have sought greater protection for HCWs by petitioning the Food and Drug Administration (FDA) for an outright ban of certain sharps devices (see “The Petition” below). The FDA has recently solicited and is considering public comment on this issue.

This white paper details factors unique to the hemodialysis (HD) setting that may influence the criteria the FDA will require for HD sharps safety. It also seeks to aid HD clinicians’ interpretation of the NSPA and its effective implementation in the HD setting. Understanding these issues is of utmost importance to the nephrology community because, without engineered safety control devices, HD HCWs are reportedly twice as likely to sustain high-risk NSI than HCWs in all other settings. The high incidence of NSI in HD is due to factors unique to HD vascular access and cannulation with arteriovenous fistula (AVF) needle sharps. Moreover, HD patients have a significantly higher prevalence of contagious bloodborne diseases than the general population, increasing the risk of

transmitting bloodborne pathogens to the HD HCW via NSI or blood sprays.

Chronic HD typically involves cannulation of a surgically created arteriovenous access with two large-gauge, hollow-bore AVF needle sharps three times per week. The HD vascular access carries arterialized blood at rates up to 2,000 mL/minute and at pressures sometimes approaching 100 mmHg. HD requires systemic anticoagulation to reduce clotting in the extracorporeal circuit. At the termination of HD, removal of the AVF needle will cause high pressure arterial blood to spurt from the cannulation site unless the HD HCW has multi-layer gauze pads pre-positioned on the site so that double-finger hemostasis pressure can be applied immediately upon AVF needle removal to staunch the bleeding. Failure to provide immediate double-finger pressure to the cannulation site presents the risk of life-threatening blood loss to the anemic, anticoagulated HD patient and the risk of contaminating the HD HCW and nearby patients with arterialized blood sprays.

The need for double-finger hemostasis pressure, however, puts the HD HCW’s fingers at severe risk of NSI and exposure to bloodborne pathogens. During removal from the HD patient, the AVF needle sharp must pass within millimeters of the HD HCW’s gauze-holding fingers.

To reduce the risk of NSI in the HD setting, a number of manufacturers have

developed engineered safety controls for AVF needle sharps—typically, sliding safety guards.

Unfortunately, the Petition asks the FDA to ban sharps devices, including guarded AVF needles, that do not “allow(s) or require(s) the worker’s hands to remain behind the needle at all times.” As the HD HCW’s finger must be placed in front of the AVF needle to apply hemostasis pressure whether a safety guard is employed or not, this criterion should be revised for AVF needles to recognize the necessity of double-finger pressure for safe HD treatment, and rather emphasize the need for an effective barrier or shield between the HD HCW’s gauze-holding fingers and the AVF needle sharp during removal from the HD patient.

More suitable criteria for evaluating safety guarded AVF needles for HD—based on considerations of ECRI (formerly the Emergency Care Research Institute), an independent, nonprofit evaluator of medical devices—are provided in this report. Features of several commercially available guarded AVF needles are evaluated under these HD-specific safety criteria.

## The Federal Needlestick Safety and Prevention Act

### Overview of the Revised OSHA Bloodborne Pathogens Standard

OSHA estimates that 5.6 million HCWs in the healthcare industry and related occupations are at risk of occupational exposure to bloodborne pathogens (BBP), including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and others.<sup>1</sup> According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 600,000 to 800,000 NSI and other percutaneous injuries occur among HCWs each year.<sup>2</sup> Studies show that nurses sustain the majority of these injuries, and that as many as one-third of all reported sharps injuries are related to needle sharps removal and/or disposal processes.<sup>1</sup>

As a result of increased attention and concern about sharps injuries, the NSPA was signed into law on November 6, 2000 and became effective April 18, 2001. Passed unanimously by the U.S. Congress, the NSPA mandated the revision of the BBP Standard to require the use of safety engineered sharps devices, with the goal of reducing NSI and exposure incidents.<sup>3,4</sup> OSHA currently inspects healthcare facilities under this new law and levies penalties for non-compliance. Indeed, employee complaints about non-compliance with the BBP Standard is a major impetus for OSHA inspections of healthcare facilities.

### Provisions of the Revised Standard

In large part, the required changes reflect the issues addressed in OSHA's 1999 compliance directive, including an increased emphasis on the use of engineering controls such as protective

devices. Together, the 1999 OSHA compliance directive and the NSPA detail the following five major requirements:

1. Employers must provide safety-engineered sharp devices and/or needleless systems to their HCWs to reduce the risk of occupational exposure to HIV, HCV, and other BBP.
2. "Engineering controls" include devices with engineered sharps injury protection that *effectively reduce* risk of an exposure incident.
3. Facilities must solicit input on evaluation and selection of safety devices from frontline HCWs.
4. "Exposure Control Plans" must document consideration and implementation of safer medical devices.
5. "Sharps Injury Log" must be maintained to help identify risk and evaluate devices.

## The Petition

In November 2000, the Public Citizen's Health Research Group (HRG) and the Service Employees International Union (SEIU) petitioned the FDA to ban certain sharps devices.<sup>5</sup> The ban criteria used in the Petition were adapted from a 1992 FDA Safety Alert, designed to warn HCWs of the risk of NSI from intravenous (IV) devices.<sup>6</sup> The Petition, however attempts to apply these criteria more broadly, and has emphasized a sub-point in the original FDA Safety Alert—namely that "the safety feature should allow or require the worker's hands to remain behind the needle at all times." The HRG and SEIU would like to ban needle sets (apparently including AVF needles) that do not meet the following criteria.

- "a fixed safety feature provides a barrier between the hands and the needle after use;

- the safety feature allows or requires the worker's hands to remain behind the needle at all times;
- the safety feature is an integral part of the device, and not an accessory;
- the safety feature is in effect before disassembly, if any, and remains in effect after disposal; and
- the device should be simple and easy to use, requiring little training."

As explained below, it is not possible for the HD HCW's hands to remain behind the needle at all times, whether the needle is guarded or not. The nature of the high pressure HD vascular access and the requirements for a large-gauge, hollow-bore needle require the HD HCW's fingers in front of the needle point during removal to deliver immediate double-finger hemostasis pressure. Thus, the criterion requiring "hands to remain behind the needle at all times" should be revised for AVF needles to recognize the necessity of double-finger pressure for safe HD treatment. A more suitable approach in the HD setting would be to emphasize the need for an effective barrier or shield between the HD HCW's gauze-holding fingers and the AVF needle sharp during removal from the HD patient.

## Needlestick Safety Devices for Hemodialysis

Because of the unique properties of the vascular access required for HD and the large-gauge, hollow-bore needles required for this treatment, HCWs in the HD setting are at a much higher risk for NSI than HCWs in other healthcare settings.

Prior to the enactment of the federal Needlestick Safety and Prevention Act, nephrology nurses sustained more sharps injuries than nurses in other specialties (0.39 vs. 0.17 percutaneous injuries per year). Of these, 47% involved blood-filled, hollow-bore needles. The overwhelming majority of these occurred during or after needle removal and could have been prevented with effective shielding of the needle point upon withdrawal.<sup>9</sup>

### High Flow, High Pressure Vascular Access and Other Clinical Considerations

Successful long-term HD depends on reliable vascular access—literally, it is the HD patient's lifeline. Typically, vascular access is provided by an arterio-venous fistula or a synthetic dialysis graft. Both of these structures join a major, high flow artery with a vein. Thus, the HD access carries high pressure arterial blood—flowing up to 2,000 mL/minute at pressures sometimes approaching 100mmHg—close to the surface of the skin.

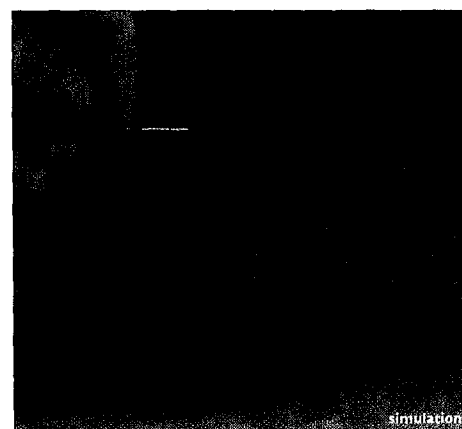
The vascular access is typically cannulated with two large-gauge (14- or 15-gauge), hollow-bore AVF needles three times per week. The high flow rates and large needle size maximize blood flow through the dialyzer. To reduce clotting in the extracorporeal circuit, HD patients are generally anticoagulated.<sup>7</sup>

While high blood flow rates and anti-coagulation increase dialysis efficiency, they pose a unique NSI risk upon removal of the AVF needle sharps. Unlike intramuscular or standard phlebotomy needles, withdrawal of AVF needles from the high pressure HD vascular access requires immediate application of double-finger pressure with multiple gauze pads to the cannulation sites to prevent arterial spurting (Figure 1).<sup>8</sup> Failure to deliver immediate double-finger pressure can cause significant blood loss—potentially life-threatening to the anemic dialysis patient. Moreover, arterial spurting or spraying presents a high contamination risk to the HD HCW and nearby patients.

To avoid the risks of arterial spurting or spraying, HD HCWs must place their gauze-holding fingers on the cannulation site, within a few millimeters of the sharp needle point during its removal (Figure 2). Thus, the HD HCWs' gauze-holding fingers are at substantial NSI risk from a blood-filled sharp during AVF needle removal and delivery of hemostasis pressure.

Data from the International Healthcare Worker Safety Center's EPINet network, a national multi-hospital database of NSI and blood exposures, confirm this risk. From 1993 to 1998, high-risk devices (blood-filled, hollow-bore sharps) accounted for twice as many injuries in the hemodialysis setting (47%) than in all other healthcare settings (23%). Further, although AVF needles represent less than 20% of the sharps used in HD, the EPINet data show that 43% of hemodialysis NSI with blood-filled needles involved AVF needles.<sup>9</sup>

Indeed, in a retrospective analysis of standard, unguarded AVF needles in the hemodialysis setting, clinic staff experienced roughly one NSI for every 12,000 cannulations.<sup>10</sup>



**Figure 1.**

Failure to provide immediate double-finger hemostasis pressure on the needle exit site upon the removal of the AVF needle resulting in arterial spurting from the high pressure HD vascular access. This presents the risk of life-threatening blood loss to the anemic, anticoagulated HD patient and the risk of contaminating the HD HCW and nearby patients with blood and BBP.



**Figure 2.**

Removal of an unguarded AVF needle demonstrating application of double-finger hemostasis pressure. During removal from the HD patient, the AVF needle sharp must pass within millimeters of the HD HCW's gauze-holding fingers.

## High Incidence of Contagious, Bloodborne Disease in the Hemodialysis Setting

Compared to the general population, the HD patient population has a higher prevalence and a more rapidly growing incidence of infections with bloodborne pathogens.<sup>11</sup> For example, the U.S. HD patient population has an HCV incidence of 8.4% compared to only 1.8% in the general population.<sup>12</sup> CDC data show that from 1985 to 2000 the proportion of HD patients in the U.S. with known HIV infection increased from 0.3% to 1.5%, a more than tenfold increase in absolute numbers.<sup>12</sup> These findings underscore the hazard of NSI in the HD setting and the need for effective needle-stick safety devices.

It is also important to realize that even NSI from “clean needles” pose a significant risk to HCWs. While the needle may be sterile, the skin and gloves of HCWs are not. Any NSI can inoculate the HCW with whatever viruses or bacteria are on their skin or gloves. HCWs may become infected with these microorganisms subsequent to accidental NSI that introduce the contaminants into the worker’s blood or tissues. This risk is particularly relevant in the HD setting, where HCV has been found on the hands of dialysis clinic staff,<sup>13</sup> HIBV antigen has been found on environmental surfaces,<sup>14</sup> and nasal carriage of *Staphylococcus aureus* among dialysis patients may be as high as 80%.<sup>15</sup>

## Interpretation of the Federal Needlestick Safety and Prevention Act for the Hemodialysis Environment

The unique requirements of high pressure HD vascular access, systemic anticoagulation, and large-gauge, hollow-bore sharp AVF needles make careful interpretation and effective implementation of the provisions of the NSPA critical for the safety of the HD HCW and HD patient.

Manufacturers of HD AVF needles have sought to develop guarded, safety

versions of their devices. Successful safety designs have focused on sheaths or guards that slide up the needle tubing, rather than engineering controls to modify the AVF needle itself. Well-designed sliding guards offer a level of **automatic needle protection**—the safety mechanism is activated during the normal course of using the device (i.e., during normal needle removal).

Because HD HCWs must apply double-finger pressure to the cannulation site immediately upon removal of the AVF needle, there is a crucial need for **pre-removal activation** of the safety device to protect the at-risk gauze-holding fingers. A safety mechanism that does not activate until after the AVF needle is removed leaves a dangerous gap in the protection of the nephrology nurse and technician. ECRI, the leading independent evaluator of medical devices, has determined that a safety feature designed to reduce NSI should be activated prior to needle sharp removal from the patient.<sup>16</sup> Thus, sliding an AVF needle guard into position such that the at-risk, gauze-holding fingers are protected by the guard’s barrier or finger shield prior to needle removal should satisfy ECRI’s preferred safety criteria. Pre-removal activation occurs if the guard serves as an effective barrier between the needle sharp and all fingers of the HD HCW’s hand that must be in front of the AVF needle during needle removal and delivery of hemostasis pressure.

Finally, because two AVF needles are typically used in HD, and because the shape, location, size, and depth of the vascular access differ tremendously, the safety designs of the guarded AVF needle must allow for safe insertion and removal of both needles in various configurations, without compromising blood flow, access survival, patient tolerance, or clinician safety.

## Criteria for Evaluating Guarded Fistula Needles

Many HD facilities have rushed to implement guarded AVF needles to comply with the new OSHA requirements. Before selecting any safety device, however, HD facilities should undergo a careful evaluation process that involves input from the HD nurses and technicians who cannulate patients and are therefore most at risk for NSI. The following evaluation criteria (Table 1) provide a basis for assessing the safety and efficacy of guarded AVF needles in the HD setting. Most importantly, the safety features should provide effective protection of the HD HCW, without modifying the basic AVF needle design or cannulation procedure, or endangering the HD patient.

### Automatic Needle Protection

In 20% of cases in which NSI occurred while safety devices were in use, HCWs had not activated the safety feature.<sup>17</sup> It is likely these injuries could have been avoided with automatic needle protection.

In the HD setting, protection from the AVF needle should occur during the normal course of removing the needle from the patient. Most importantly, the guard should have a feature that protects the gauze-holding fingers during needle removal and allows for the immediate application of double-finger pressure upon needle removal (Figure 3). Thus, automatic protection should be directed at reducing injury of the HCW’s finger(s) that are most at-risk. The safety mechanism should enclose the needle upon removal and during subsequent disposal. Ideally, a one-step locking mechanism should ensure immediate, simple, and complete protection. Upon deployment, the guard should completely house the blood-filled needle; the safety design

**Table 1:** Evaluation Criteria for Guarded AVF Needles

### **Automatic Needle Protection**

- Guard (safety device) is activated during the normal course of removing fistula needle
- Guard is an integral part of the needle set
- Guard provides one step locking to ensure automatic protection during needle removal and disposal
- Activated guard effectively prevents fingers from entering the guard
- Guard serves as an automatic protective barrier between the needle and gauze-holding fingers during needle removal and allows immediate application of double-finger pressure at the cannulation site upon needle removal
- Needle can enter guard with bevel orientated up or down; locking mechanism can be activated with bevel in either orientation

### **Pre-removal Activation**

- Sliding the guard into pre-removal position places a protective barrier between the cannulated needle and the gauze-holding fingers
- The needle can be withdrawn from the pre-removal position with one hand in a smooth, one-step motion without compromising ability to deliver immediate double-finger pressure at the cannulation site

### **Design Requirements & Use**

- Guard does not increase the rigid length or diameter of needle hub or make other changes that alter conventional cannulation approach
- Guard does not restrict overall flexibility of the needle set or limit selection of cannulation site; safety design does not limit ability to cannulate potential fistula/graft configurations
- Guard allows standard cannulation, taping, and hemostasis procedure
- Safety design allows visualization of flashback upon proper needle insertion and visualization of needle during removal
- Safety design does not increase infiltration rate
- Activation of safety device does not cause lateral or vertical movement of the sharp needle point in the vascular access during needle removal or increase the risk of fistula/graft damage or hematoma
- Manufacturer provides clear instructions for use and high quality product training and support materials

### **Effectiveness Data**

- Published comparative data demonstrate effectiveness of the safety device to reduce NSI in the hemodialysis setting





**Figure 3.**

Use of an effective barrier between the AVF needle sharp and gauze-holding fingers provides automatic needle protection upon needle removal, while allowing immediate application of double-finger pressure at the cannulation site.

should not allow the sharp tip to extend past the base of the guard, offering only incremental protection.

#### **Pre-removal Activation**

Epidemiologic data demonstrate that the majority of NSI in the HD environment occur during or shortly after the removal of unguarded AVF needles from the patient.<sup>9</sup> It is likely that these injuries could be dramatically reduced by pre-removal activation of needle safety devices.

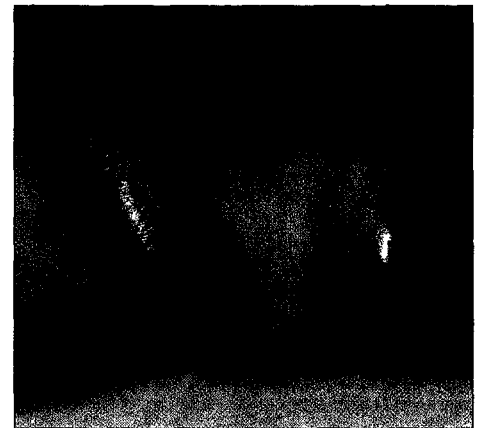
Positioning the guard above the inserted AVF needle (pre-removal activation) should place a protective barrier or shield between the needle and the gauze-holding fingers. From this pre-removal position, the needle should be easily and safely withdrawn by pulling on the needle tubing with one hand in a smooth, one-step motion that does not hamper the HCW's ability to deliver immediate double-finger pressure at the needle exit site.

#### **Design Requirements & Use**

The effectiveness of any medical safety device is dependent on proper use. A simple, intuitive device may optimize worker safety because of its ease of use.

The safety features of a well-designed guarded AVF needle provides effective protection without modifying basic needle design, standard cannulation, or hemostasis procedure. Specifically, safety devices should not alter the extremely short rigid hub design crucial to maintaining low lever-arm forces on the cannulated sharp needle tip—a standard design of AVF needles for more than 20 years—to avoid risks of fistula/graft damage and hematoma formation. Designs that lengthen the rigid portion of the needle and hub also limit the number of available cannulation sites to long, straight fistulas/grafts. This consideration becomes most important for upper arm fistulas and other tortuous fistula configurations that provide restricted needle sites or inconvenient cannulation angles (Figure 4).

Further, safety devices should not interfere with standard taping of the needle set. Similarly, safety devices should not interfere with the HCW's visual cues of successful needle insertion (i.e., flashback) or needle removal (i.e., full visualization of needle upon removal). The safety device should not increase the infiltration rate during needle insertion or damage the vascular access upon removal. Safety designs that promote side-to-side or up-and-down motion of the AVF needle sharp during removal are flawed, as they may damage the HD patient's fragile fistula or graft.



**Figure 4.**

Tortuous upper arm fistula. Contorted vascular access configurations provide restricted needle sites or inconvenient cannulation angles. AVF needle designs with an extended rigid needle-hub segment reduce overall flexibility of the needle set and thereby limit the selection of cannulation sites. Shorter needle-hub designs provide a shorter "turning radius," maximizing options for needle placement.

Availability and quality of detailed product training materials and on-site support should be critical considerations for the selection of any medical device. These considerations are particularly important in the HD setting, where staff turnover is extremely high. Likewise, the reliability of the manufacturer should be an important factor when evaluating safety devices.

#### **Effectiveness Data**

Under the federal NSPA, safety devices must effectively reduce risk of NSI and exposure incidents. Accordingly, published comparative data demonstrating efficacy of a safety feature to reduce NSI in the HD setting should become the standard for evaluating guarded AVF needles. In light of the paucity of published reports, HD clinics should be encouraged to review their own Sharps Injury Log to compare safety of various AVF needle designs.

## Clinical Study of Efficacy of Guarded Fistula Needles in the Reduction of NSI

The federal NSPA requires implementation of needles with safety features that effectively reduce exposure incidents through NSI, yet does not define how efficacy should be determined. Efficacy studies should help HD facilities identify needle safety devices with demonstrated NSI reduction.

To date, only one comparative study demonstrating efficacy of a guarded AVF needle to reduce NSI in the HD setting has been reported in the clinical literature.<sup>10</sup>

Conducted at five affiliated dialysis clinics over a 24-month period, the study was designed to compare the NSI rate of conventional, unguarded AVF needles to a commercially available guarded AVF needle. All participating clinics had an existing system for reporting NSI and access to historical data; all clinics had used unguarded AVF needles prior to the study period.

Data collected during the retrospective and prospective phases of the study included the number of all unguarded or guarded AVF needles used, and the number of NSI that occurred with their use. NSI data were collected starting with needle removal from the patient through disposal of the device. Disposal data

captured NSI reported by HD HCW, including disposal workers and others in the HD facility.

NSI data for unguarded AVF needles were collected retrospectively for 15 months beginning January 1, 1999. The prospective phase of the study was conducted during the nine-month period beginning April 1, 2000. For this phase, use of unguarded AVF needles was discontinued and only one guarded AVF needle design was used.

The guarded needle system (Medisystems AV Fistula Needles with MasterGuard® Anti-Stick Needle Protector, 14- to 18- gauge with back-eye, clamp, 12" tubing) included a slotted guard attached to a conventional, winged Medisystems AVF needle. The sliding guard is an integral part of the needle set, yet is separate from the winged AVF needle, permitting standard cannulation and site selection. In their normal hemostasis position, the gauze-holding fingers activate the guard by holding a forward extension of the guard (i.e., pre-removal activation) that also acts as a finger shield for the gauze-holding fingers (Figure 3). With the guard held stationary by this means, the needle is withdrawn into a lock in the guard (i.e., automatic needle protection) by a normal needle removal technique—pulling on the tubing.

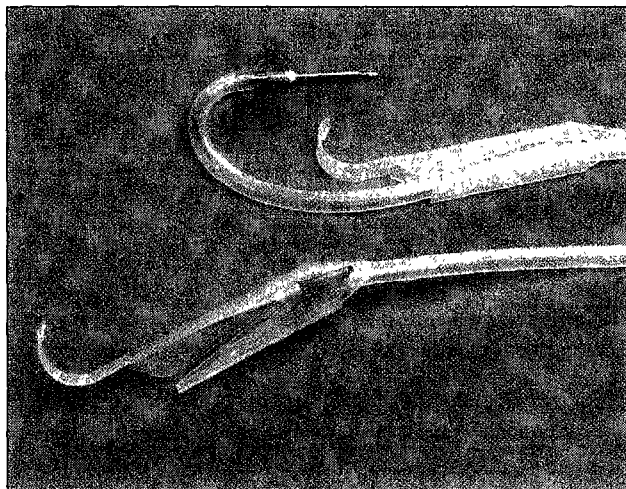
During the retrospective phase, 107 clinical staff and 273-331 HD patients participated in the study, with staff performing 81,534 unguarded AVF needle cannulations and removals. In the prospective phase, 128 clinical staff and 331-370 HD patients were involved in 54,044 guarded AVF needle cannulations and removals. Seven NSI occurred with unguarded AVF needles, while not a single NSI occurred with the guarded AVF needles.

Overall, NSI reduction was 100% for the Medisystems guarded AVF needle versus the unguarded AVF needle in this study, with >54,000 cannulations and removals in each group ( $p<0.029$ ).<sup>10</sup> The unique FingerShield™ Anchor—which is engineered to protect the pressure fingers during and immediately after needle removal—appears to have helped eliminate NSI in these HD settings.

Additional efficacy studies are necessary to further assist hemodialysis facilities in their selection of a guarded fistula needle that will reduce the risk of NSI among their clinical staff.

## Guarded Fistula Needles

A number of guarded AVF needle sets are currently available to help HD facilities reduce NSI. Figures 5-8 present four guarded AVF needles and review their respective safety features in light of the evaluation criteria suggested above.



**Figure 5.**

MasterGuard® Anti-Stick Needle Protector (Medisystems Corporation, Seattle, WA).

**Evaluation—MasterGuard® Anti-Stick Needle Protector**

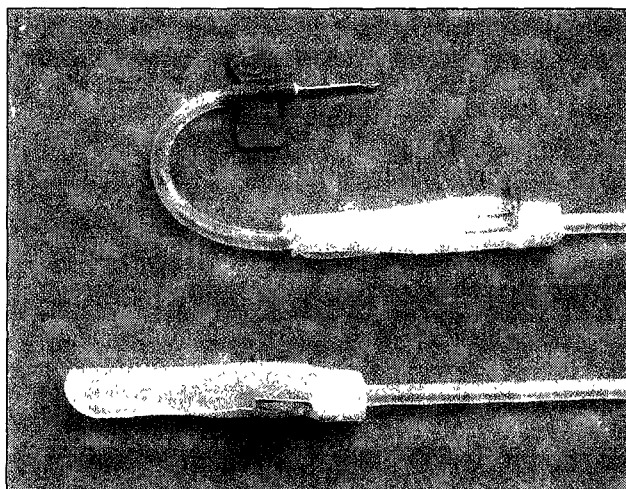
**Automatic Needle Protection:** Integrated guard activated during normal needle removal; activated guard houses needle completely; one-step locking ensures needle tip not exposed; FingerShield™ Anchor provides automatic protective barrier between the needle and gauze-holding fingers, allowing safe, immediate application of double-finger pressure upon needle removal



**Pre-removal Activation:** Sliding guard forward into pre-removal position places the FingerShield Anchor between the needle sharp and gauze-holding fingers

**Design Requirements & Use:** Standard needle-hub length; standard cannulation and taping procedures; needle removed by pulling on needle tubing; wings slide into one-step lock (audible indication of locking); standard hemostasis pressure (index and middle finger); clear guard allows visualization of flashback and removed needle; videos, training materials, and in-service support available

**Effectiveness Data:** Efficacy study demonstrated 100% reduction in NSI with MasterGuard® Anti-Stick Needle Protector compared to unguarded AVF with >54,000 cannulations/removals in each group ( $p < 0.029$ )<sup>10</sup>



**Figure 6.**

JMS Platypus™ AV Fistula Needle Guard (JMS North America Corporation, Hayward, CA).

**Evaluation—JMS Platypus™ AV Fistula Needle Guard**

**Automatic Needle Protection:** Integrated guard slides forward during normal needle removal; activated guard houses needle completely after removal; two-step locking ensures needle tip not exposed; no automatic protective barrier between the needle and gauze-holding fingers

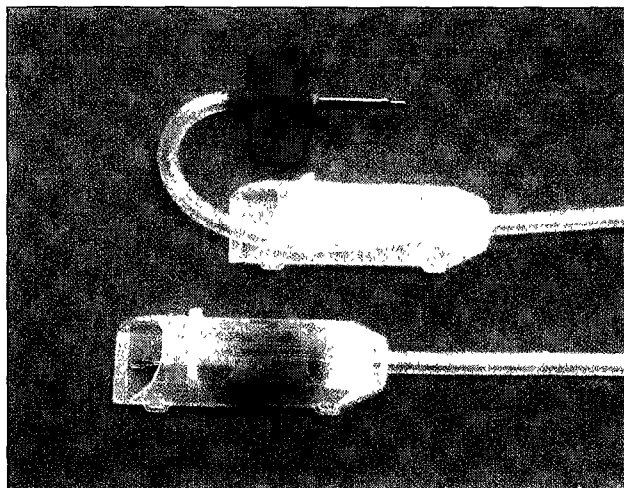
**Pre-removal Activation:** Sliding guard forward into pre-removal position does not place a barrier between the needle



sharp and gauze-holding fingers; index finger and thumb grip guard's sides during needle removal; gauze-holding fingers (middle and fourth finger) remain at risk of NSI during needle removal

**Design Requirements & Use:** Standard needle-hub length; standard cannulation and taping procedures; needle removed by pulling on needle tubing; wings slide into two-step lock (audible indication of locking); modified hemostasis pressure required; opaque guard may impair visualization of flashback and removed needle; videos, training materials, and in-service support available

**Effectiveness Data:** Not available



**Figure 7.**

JMS WingEater™ AV Fistula Needle Guard (JMS North America Corporation, Hayward, CA).

**Evaluation—JMS WingEater™ AV Fistula Needle Guard**

**Automatic Needle Protection:** Integrated guard slides forward during normal needle removal; activated guard houses removed needle in open-ended container (protection is incremental, i.e., sharp needle tip may remain exposed; finger may enter container); no automatic protective barrier between the needle and gauze-holding fingers; needle enters guard in bevel-up orientation only

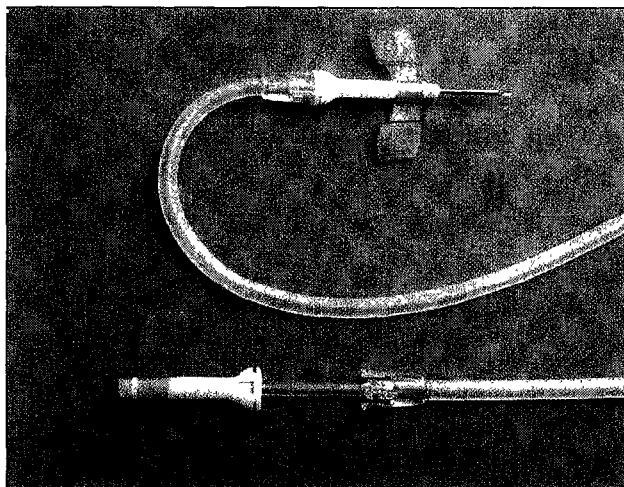
**Pre-removal Activation:** Sliding guard forward into pre-removal position does not place a barrier between the



needle sharp and gauze-holding fingers; index finger rests above guard during needle removal; gauze-holding fingers (middle and fourth finger) remain at risk of NSI during needle removal

**Design Requirements & Use:** Standard needle-hub length; standard cannulation and taping procedures; needle removed by pulling on needle tubing; wings slide into open-ended container (no audible indication of locking); significant lateral movement of needle sharp possible as wings enter open-ended container presents risk of damaging fistula or graft during needle removal; modified hemostasis pressure required; clear guard allows visualization of flashback and removed needle; videos, training materials, and in-service support available

**Effectiveness Data:** Not available



**Figure 8.**

Nipro SafeTouch™ Fistula Needle (Nipro Medical Corporation, Miami, FL).

**Evaluation—Nipro SafeTouch™ Fistula Needle**

**Automatic Needle Protection:** Extended hub (wing protector) slides forward during needle removal; deployed guard houses needle completely within hub/wing protector; no automatic protective barrier between the needle and gauze-holding fingers

**Pre-removal Activation:** Pre-removal activation (pressing sides of stopper at base of hub) releases hub/wing protector; pulling tubing back into hub/wing protector does not place a barrier between the needle sharp and gauze-holding fingers; index finger holds wing



or hub/wing protector during needle removal; gauze-holding fingers (middle and fourth finger) remain at risk of NSI during needle removal

**Design Requirements & Use:** Extended needle-hub length may limit vascular access configurations that can be cannulated by increasing the “turning radius” of the needle set; modified taping procedure (wing protector remains taped during needle removal); needle removed by pulling on needle tubing (audible indication of locking); needle slides into hub/wing protector; modified hemostasis pressure; white extended hub/wing protector impairs visualization of flashback and removed needle; videos, training materials, and in-service support available

**Effectiveness Data:** Not available

## Summary

The federal NSPA offers non-specific guidelines for protecting HCWs from NSI and exposure to bloodborne pathogens. Interpreting the NSPA in the context of HD care gives rise to several clear criteria for the evaluation of guarded AVF needles. Of primary consideration is the need for automatic needle protection in the HD setting. With automatic AVF needle protection, the safety mechanism is activated during the normal course of needle removal from the HD patient.

The HD nurse or technician must place the gauze-holding fingers directly in front of the needle during its removal to deliver immediate double-finger pressure to avoid arterial spurting or spraying and excessive blood loss. Sliding an effective guard into pre removal position above the needle (pre-removal activation) should provide a protective barrier between the needle and gauze-holding fingers during needle removal, thereby shielding the at-risk fingers, while allowing immediate application of double-finger pressure at the needle exit site.

Importantly, the safety device should not increase the rigid hub length or diameter, which increases lever-arm forces on the sharp needle point within the vessel and limits cannulation site selection to a relative few straight sections of fistulas and grafts. The safety device should allow the nephrology clinician to follow conventional cannulation and gauze-holding procedures without increasing infiltration rates or damaging the access due to impaired visualization of the needle or lateral movement of the AVF needle during removal.

Further, ease of use—which corresponds closely with the quality of training materials and on-site support—should be given significant weight during the selection process. If users find the device difficult or awkward to use, they may fail to activate the mechanism correctly or they may choose not to use the device at all.

Finally, published comparative data from clinical studies designed to determine effectiveness of guarded AVF needles engineered to reduce NSI in the hemodialysis setting provide a scientific basis for the evaluation of safety designs.

As demonstrated in the single efficacy study available to date,<sup>10</sup> an effective safety design can dramatically reduce NSI in the HD environment. Careful evaluation and thoughtful selection of guarded fistula needles can help hemodialysis facilities achieve an important goal—protection of the nephrology nurse and technician.

## Conclusion

Legislation such as the NSPA and independent evaluation of resulting sharps safety devices by ECRI are valuable means to increase HCW and patient safety and to reduce the economic burden associated with NSI and exposure to BBP. However, petitions, such as the one currently before the FDA, while well intentioned, do not take into account the clinical considerations and technical requirements associated with AVF needle removal from the high pressure HD vascular access.

The HRG/SEIU Petition asks the FDA to ban sharps devices, including guarded AVF needles, that do not “allow(s) or require(s) the worker’s hands to remain behind the needle at all times.” As the HD HCW’s finger must be placed in front of the AVF needle to apply hemostasis pressure whether a safety guard is employed or not, this criterion should be revised for AVF needles to recognize the necessity of double-finger pressure for safe HD treatment, and rather emphasize the need for an effective barrier or shield between the HD HCW’s gauze-holding fingers and the AVF needle sharp during removal from the HD patient.

Evaluating guarded AVF needles using the HD-specific safety criteria described herein and in accordance with ECRI criteria will assist policymakers and clinicians to identify sharps safety designs most appropriate for the HD setting.

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